A complete magnetic radiation free procedure for sentinel lymph node localization

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28812

Source
Nationaal Trial Register

Brief title
LowMag

Health condition

Sentinel Lymph Node Biopsy in breast cancer and melanoma patients. Outcomes are potentially of benefit for more solid cancer patients.

Sponsors and support

Primary sponsor: University of Twente, Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Technologische Wetenschappen (STW)

Intervention

Outcome measures

Primary outcome

1. The proportion of sentinel nodes correctly detected with the magnetic technique

(magnetometer) as compared to the combined technique (visually and/or using the gammaprobe).
2. The proportion of patients in which the sentinel lymph nodes could successfully be detected (detection rate) using the magnetometer.

3. The number and percentage of sentinel lymph nodes correctly diagnosed to be metastatic using ex vivo MRI.

4. The number and percentage of sentinel lymph nodes correctly diagnosed to be non-metastatic using ex vivo MRI.

Secondary outcome

5. The iron content in the dissected lymph nodes (average, minimum and maximum) in relation to the image quality;

6. The image parameters indicative for the presence of lymph node metastases;

7. The requirements in detection depth and minimally detectable mg iron per node for future magnetometers.

Study description

Study objective

The sentinel lymph nodes (SLN) are the first lymph nodes to drain the tumor site and therefore the first lymph nodes to bare metastases. Hence the importance to investigate these lymph nodes to define the best treatment strategy. Currently, in a.o. breast cancer and melanoma patients, the sentinel lymph nodes are intraoperatively detected, both visually and by using a gamma probe, following the subsequent injections of radioactive tracer (Tc 99-m nanocolloid) and blue dye (Patent Blue). Histopathological investigation of the resected sentinel lymph nodes should then confirm the presence or absence of metastases. The conventional methods for sentinel lymph node biopsy suffer from disadvantages, such as the use of radioactive materials and the fact that node-positive patients require multiple surgical procedures. At the NeuroImaging (NIM) group of the University of Twente, we investigate a magnetic, radiation-free, procedure for sentinel lymph node detection and evaluation. Several aspects of this procedure have been investigated in separate studies. Results were promising, showing a detection rate of the sentinel node non-inferior to the detection rate with the existing technique and proving the feasibility to visualize the sentinel nodes in preoperative MRI. However, the doses and volume of the injected magnetic tracer (SuperParamagnetic Iron Oxide particles, SPIO), was relatively high. The high dose of iron potentially leads to difficulties in evaluating lymph nodes with small metastases and to substantial skin staining. Additionally, the high volume of injected tracer might in some cases lead to a non-physiological uptake of iron in the lymph vessels, reducing the reliability for

detecting (solely) sentinel lymph nodes. In this study, the aim is to investigate the feasibility of using low dose SPIO (50x lower than the previously safely used dose) for both preoperative evaluation and intraoperative detection of the sentinel lymph node in breast cancer patients.

Study design

Interim analysis and evaluation of the protocol after:

every 10 performed procedures

every 5 completed procedures on patients with macrometasastes

every 5 completed procedures on patients without metastases

Intervention

Two peritumoral injection of SPIO (SIENNA+), 1 mg in 1 mL following the injection of TC99m and lymphoscintigraphy.

The intraoperative detection of the SPIO accumulation in SLNS by a handheld magnetometer in addition to the conventional detection of accumulated TC99-m nanocolloid by the gammaprobe.

The imaging part of this study is performed ex vivo and post-surgery.

Contacts

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Eligibility criteria

Inclusion criteria

Adult, clinically (palpation and ultrasound) node negative, patients that are diagnosed with invasive breast cancer or high grade ductal carcinoma in situ and that are scheduled for a two-day SLNB procedure and that gave informed consent for participation to the study;

Exclusion criteria

1.Patients incapable of giving informed consent for participation to the study;

2.Intolerance / hypersensitivity to iron or dextran compounds;

3.Patients that have received neoadjuvant chemotherapy in the period of 5 years prior to this study.

4.Pregnant or lactating patients

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-01-2015
Enrollment:	50
Type:	Unknown

Ethics review

Positive opinion

Date:	22-10-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4713
NTR-old	NTR4858
Other	NL49285.044.14 : METC TWENTE P14-32

Study results